K062878

Advanced Imaging Solutions, LLC

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Summary

JUN 27 2007

Summary Preparation Date

3 Dec 2004

Company Identification

Advanced Imaging Solutions, LLC
43731 N. 15th St West
Lancaster CA 93534

Contact Person

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Device Identification

Trade Name:	EZPACS®
Common Name:	Picture Archiving Communications System (PACS)
Classification:	Class II (Product Code: LLZ)

Predicate Devices

DirectView by Kodak (K030781 approved 5/29/03)
IMPAX by Agfa (K022292 approved 9/12/02)

Description of Device

EZPACS® is a PACS system that runs on off-the-shelf monitors and PCs running the Microsoft Windows® operating system. It consists of software that displays images and provides functions for image manipulation, enhancement, compression and quantification.

Intended Use

EZPACS® is intended for use by radiologists (for primary diagnosis), and other medical professionals.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Substantial Equivalence

	EZPACS	**IMPAX**	**DirectView**
Commercial PCs running Windows® O/S	yes	yes	yes
Commercial monitors	yes	yes	yes
Multi-monitor support	yes	yes	yes
JPEG/wavelet compression	yes	yes	yes
DICOM conformance	yes	yes	yes
Measurement tools (ROI, distance, angle)	yes	yes	yes
Viewing tools (window/level, magnify, pan, annotation	yes	yes	yes
Comparison cases	yes	yes	yes
Cine/stack view	yes	yes	yes
Supports teleradiology	yes	yes	yes
3D viewing	yes	yes	yes

The EZPACS® software is substantially equivalent to IMPAX and DirectView in functions, features, intended use, hardware, safety and effectiveness. Any differences have no significant effect on safety and effectiveness.

Conclusion

The EZPACS® software has the same intended use, features, safety and effectiveness as IMPAX and DirectView, therefore it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 27 2007

Ray Hashemi, M.D., Ph.D.
CEO
Advance Imaging Solutions, LLC
43731 N. 15th St. West
LANCASTER CA 93534

Re: K062878
Trade/Device Name: EZPACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 14, 2007
Received: May 16, 2007

Dear Dr. Hashemi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

Re: EZPACS

510(k)# K062878

EZPACS® is intended for use by radiologists (for primary diagnosis), and other medical professionals who needs access to radiological images and reports.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

[x] Prescription Use

[ ] Non Prescription Use

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062878